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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,564

04/27/2006

Zhongyi Li

71342-PCT-US/JPW/JW

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EXAMINER

PAGE, BRENT T

ART UNIT

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1638

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/577,564	LI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	BRENT PAGE	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18,20,24,37 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 7,15-18,20,24 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-14 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/2006, 9/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 03/23/2009 is acknowledged. The traversal is on the ground(s) that claim 15 depends from claim 2 and that the grain "further" comprises a null mutation of SBEIIa and SBEIIb, that claim 16 has no basis for a restriction, and that the inventions are not independent and do not pose a serious search burden. This is not found persuasive because, initially, claim 15 does not clarify claim 2, particularly in view of the fact that claim 2 is restricted to an introduced nucleic acid which inhibits SBEIIa and SBEIIb, as indicated in the restriction requirement mailed out on 02/19/2009. Therefore claim 15 does not further define the elected portion of claim 2, but the non-elected portion, and therefore is withdrawn by the Examiner as being drawn to non-elected subject matter. Claim 16, further limits generic claim 1 to comprising an allelic variant and is restricted on the basis that there are several methods and materials that are used to arrive at the grain claimed in claim 1. The limitation of claim 16, drawn to an allelic variant is not part of group I, because group I is drawn to introduced nucleic acids. Claim 16 is not drawn to this invention, and is similarly withdrawn by the Examiner as being drawn to non-elected subject matter. The search burden in the instant Inventions, is present because a search for natural variants/ and or mutagenized SBEIIa, or SBEIIb genes would not encompass a search for anti-sense nucleic acids introduced to suppress SBEIIa or SBEIIb, for example, neither would a search for introduced inhibitors encompass a search for naturally occurring or mutagenized SBEIIa or SBEIIb genes. Furthermore, it is pointed

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out that different product claims, i.e. starch granules, do not have the same features and properties of the elected product claims, i.e. rice grain since the starch granules would not comprise the nucleic acid sequences of the instant invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-18, 20, 24, 37 and 43 are pending. Claims 7, 16-18, 20, 24 and 37 are withdrawn by the Examiner as being drawn to non-elected subject matter. Claims 1-6, 8-14 and 43 are examined herein on the merits.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. There are 4 instances of hyperlinks in the specification as currently written, 3 in paragraph 89 and 1 in paragraph 168. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Rejections - 35 USC § 112-scope of enablement***

Claims 1-6, 8-14 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reduction of SBEIIa using a specific sense and anti-sense construct for exons 1,2 and 3 along with intron 3 in the sense orientation and exons 1,2,3 and 4 of the SBEIIa enzyme in the antisense orientation, does not reasonably provide enablement for any exogenous nucleic acids expressing any other inhibitors of SBEIIa or SBEIIb. The specification also does not

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provide any guidance as to any other genetic variation leading to a reduced level of SBEIIa or SBEIIb. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a rice grain and a rice plant comprising any genetic variation leading to a reduced level of starch branching enzyme IIa protein and/or starch branching enzyme IIb protein of the rice grain of any genetic background wherein the genetic variation is an exogenous nucleic acid expressing an inhibitor of SBEIIa and/or SBEIIb.

In contrast the specification provides guidance only for the reduction of SBEIIa using a specific sense and anti-sense construct for exons 1,2 and 3 along with intron 3 in the sense orientation and exons 1,2,3 and 4 of the SBEIIa enzyme in the antisense orientation. The specification does not provide guidance for any exogenous nucleic acids expressing any other inhibitors of SBEIIa. The specification also does not provide any guidance as to any other genetic variation leading to a reduced level of SBEIIa.

The synthesis of starch in plants is complex and unpredictable. In a review of the regulation of starch metabolism in plants Tetlow et al (2004 Journal of Experimental Botany 55(406):2131-2145) discuss the developments that help understand the regulation of starch metabolism in higher plants. Tetlow et al disclose that the function of any particular starch depends on the type of plastid it is synthesized in and the type of plant tissue it is derived from (see page 2131 Column 2, lines 3-5). Tetlow et al also disclose that only a few genetic variations that lead to known phenotypes are even

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known for starch branching enzymes as evidenced by the statement "To date, only mutations in SBEII isoforms give clear phenotypes, and in monocots this is confined to SBEIIb mutants" (see page 2134 second column, last paragraph). Furthermore the affect these variations have on starch derived from the endosperm is unpredictable. Tetlow et al disclose a mutant of SBEIIa that displayed a clear phenotype in leaf starch but showed no alterations in the storage starch of the endosperm (See page 2134 Column 2, last paragraph, for example). Tetlow et al further disclose that other genes are capable of affecting the expression of at least SBEIIb, but not all of these genes are known (see page 2135, 1<sup>st</sup> column, 3<sup>rd</sup> paragraph, for example). Without a clear guidance as to the specific genetic variation, it would be undue experimentation to evaluate all genetic variations of all genes affecting the level of SBEIIa and SBEIIb enzymes as broadly claimed.

It is also unpredictable what affect any anti-sense RNA will have on the expression of SBEII forms. Tetlow et al disclose that alternative splicing of a SBEII form in *Phaseolus vulgaris* causes alteration in the properties of the enzyme (see page 2135, 1<sup>st</sup> Column, 1<sup>st</sup> paragraph, for example). The art is silent on alternative splicing in SBEII forms in rice, but given the disclosure by Tetlow et al, it would be undue experimentation to evaluate all RNA fragments for their ability to affect the expression of SBEIIa. Absent a SEQ ID NO, the effect of any length RNA molecule over any portion of the SBEIIa gene would be unpredictable. The Examiner notes that the claims are further not specific to antisense nucleic acids of SBEII enzymes and that the

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unpredictability of antisense nucleic acids to any other genes in affecting SBEIIa expression is encompassed in the discussion above.

Given the state of the art, the disclosure by Tetlow et al, the lack of working examples, the lack of guidance as discussed above, and the unpredictability as discussed above, it would be undue experimentation for one of skill in the art to isolate and evaluate all genetic variation in all inhibitors that would lead to reduced SBEIIa expression as broadly claimed.

***Claim Rejections - 35 USC § 112-written description***

Claims 1-6, 8-14 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a rice grain and a rice plant comprising any genetic variation leading to a reduced level of starch branching enzyme IIa protein in the the rice grain of any genetic background wherein the genetic variation is an exogenous nucleic acid expressing an inhibitor of SBEIIa.

In contrast the specification only describes the reduction of SBEIIa using a specific sense and anti-sense construct for exons 1,2 and 3 along with intron 3 in the sense orientation and exons 1,2,3 and 4 of the SBEIIa enzyme in the antisense orientation. The specification does describe any other exogenous nucleic acids

expressing any other inhibitors of SBEIIa. The specification also describe any other genetic variation leading to a reduced level of SBEIIa.

The specification does not describe or in any other way disclose the types of genes or gene function, or the types of sequence that is necessary for the claimed function of inhibiting the expression of SBEIIa or SBEIIb. When the specification does not describe a representative number of the claimed embodiments, Applicant is required to describe the structural features that are required for the claimed function. However, the instant specification does not describe the structural features that are necessary for genes other than SBEIIa for the inhibition of SBEIIa or SBEIIb, nor does the specification describe which sequences present even in SBEIIa would be required to inhibit the expression of SBEIIa and/or SBEIIb.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*



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Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the genus of sequences required for making the claimed wheat grain, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in *Federal Register*/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

***Claim Rejections - 35 USC § 103***

Claim 1-6, 8-14 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Broglie et al (US Patent 6376749, filed February 25, 1999).

The claims are drawn to a ricegrain and a rice plant comprising any genetic variation leading to a reduced level of starch branching enzyme IIa protein in the rice grain of any genetic background wherein the genetic variation is an exogenous nucleic acid expressing an inhibitor of SBEIIa.

Broglie et al teach a maize plant transformed with an antisense construct for the inhibition of starch branching enzyme activity resulting in corn with increased amylose content (see claims 1-13 and Table 3, for example).

Broglie et al do not teach a rice plant or grain transformed with an antisense construct. However, Broglie et al does suggest the use of rice in paragraph 2 of the background of the inventions stating that starch isolated from rice may meet the functionality requirements (see 2<sup>nd</sup> paragraph under Background of Invention).

Given the results of Broglie et al, and the suggestion by Broglie et al that the sequences could be used in rice, it would have been obvious to one of ordinary skill in the art to use the the anti-sense construct taught by Boglie et al as suggested by Broglie et al by transforming rice to modify the starch content of the rice. The starch content of the rice grain is an obvious design choice as different rice grains with different starch contents may be selected for modification. The amylose content of the rice grain is a property that would naturally follow from the transformation of the rice with the genetic modifications taught above.

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The claimed measurements of the rice grain are properties that would necessarily follow absent evidence to the contrary from the transformation of wheat with the constructs taught above.

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Anne Marie Grunberg/  
Supervisory Patent Examiner, Art Unit 1638